

REMARKS

The Final Office Action mailed on October 10, 2001, has been received and reviewed. Claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 are currently pending in the application. Claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 stand rejected. Applicant respectfully requests reconsideration of the application.

35 U.S.C. § 103(a) Obviousness Rejections

Claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 stand rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over various combinations of U.S. Patent No. 5,482,598 issued to Isaka et al. ("Isaka"), U.S. Patent No. 5,885,869 issued to Turner et al. ("Turner"), U.S. Patent No. 5,611,846 issued to Overton et al. ("Overton"), U.S. Patent No. 5,132,012 issued to Miura et al. ("Miura"), U.S. Patent No. 5,663,488 issued to Wang et al. ("Wang"), U.S. Patent No. 5,882,496 issued to Northrup et al. ("Northrup"), U.S. Patent No. 5,571,410 issued to Swedberg et al. ("Swedberg"), and U.S. Patent No. 5,536,382 issued to Sunzeri ("Sunzeri").

M.P.E.P. 706.02(j) sets forth the standard for a 35 U.S.C. § 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Patent Office bears the burden of establishing the *prima facie* case of obviousness. *In re Linter*, 458 F.2d 1013, 173 U.S.P.Q. 560 (CCPA 1972).

Obviousness Rejection Based on Isaka in View of Turner

Claims 105-107 stand rejected under Section 103 as being unpatentable over Isaka in view of Turner for reasons of record. Applicant respectfully traverses this rejection, as hereinafter set forth.

Isaka discloses a chromatographic separation device that includes a silicon substrate and a only a single porous microchannel formed in the silicon substrate.

Turner teaches a method of uniformly doping hemispherical grain polycrystalline silicon in a semiconductor substrate. The method is used to dope the top, roughened polysilicon layer without doping other layers of the semiconductor substrate, such as the bottom polysilicon layer.

Claim 105 recites an ultrasmall slow channel device that comprises a flow inlet and a flow channel connected to the inlet. The flow channel comprises a matrix formed of hemispherical grained silicon.

It is respectfully submitted that the obviousness rejection of claim 105 is improper because the references do not provide a motivation or suggestion to combine and because the references do not teach or suggest all the limitations of claim 105. The cited references do not teach or suggest all the limitations of claim 105 because neither Isaka nor Turner teach a flow channel comprising a matrix formed of hemispherical grained silicon. Rather, the microchannel of Isaka is formed in the silicon substrate while Turner uses hemispherical grained silicon to form the layer in the semiconductor substrate.

In addition, there is no motivation to combine the references because neither Isaka nor Turner teaches or suggests using hemispherical grain polycrystalline silicon in a chromatographic apparatus. Since Turner relates to fabricating semiconductor substrates, it does not contemplate using hemispherical grain polycrystalline silicon to separate the constituents of a sample in a chromatographic device, electrophoretic apparatus, or other separation device. In addition, Isaka does not suggest using hemispherical grain polycrystalline silicon as the porous matrices in the chromatographic separation device.

Claims 106 and 107 are allowable, among other reasons, as depending from allowable claim 105. Claim 106 is further allowable because neither Isaka nor Turner disclose that the flow channel comprises a stationary phase disposed on the hemispherical grained silicon. Claim 107

is further allowable because neither Isaka nor Turner disclose that the stationary phase disposed on the hemispherical grained silicon is silicon dioxide.

Obviousness Rejection Based on Isaka in View of Overton

Claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton for reasons of record. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka are summarized above.

Overton discloses a miniaturized gas chromatograph that includes, among other things, a tubular column of conventional configuration. Overton discloses that the gas chromatograph may include multiple columns that are connected to one another by pneumatic valves. A sample to be separated may be directed onto the column, which is chosen to be appropriate for the type of analysis being performed, by the pneumatic valves.

Independent claim 1 recites a sample separation apparatus that includes a substrate and matrices formed in the substrate. The matrices comprise at least two distinct, unconnected porous regions that extend at least partially across the substrate. The sample separation apparatus also includes at least one detector fabricated on the substrate and associated with at least one of the at least two porous regions. Applicant respectfully submits that the obviousness rejection of claim 1 is improper because the criteria of Section 103 have not been established by the Patent Office.

First, the obviousness rejection of claim 1 is improper because there is no suggestion or motivation in Isaka and Overton to combine the references to produce the claimed invention. Isaka teaches a chromatographic separation device that includes a single, porous column formed in a silicon substrate. Overton teaches a miniaturized gas chromatographic separation device that includes conventional columns. These columns typically comprise single-channeled tubular members. The examiner asserts that one of ordinary skill in the art would be motivated to combine the teachings of Isaka and Overton because Overton discloses that various configurations of columns may be used for various applications. Office Action of December 10,

2001, p.5-6. However, the mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01. Isaka does not suggest the desirability of a sample separation apparatus device that comprises multiple columns formed in the silicon substrate. Further, Overton does not suggest the desirability of multiple columns for chromatographic applications similar to the chromatographic separation device of Isaka.

In addition, even if the cited references taught that all of the aspects of the claimed invention were individually known in the art, a *prima facie* case of obviousness would not be established unless an objective reason to combine the references was present. M.P.E.P. § 2143.01. Neither Isaka nor Overton provide an objective reason to combine the references and, therefore, any suggestion to one of ordinary skill in the art to combine the teachings of Isaka and Overton could only have been gleaned from the disclosure of the above-referenced patent application.

Second, the obviousness rejection of claim 1 is improper because there is no reasonable expectation of success. The examiner asserts that one of ordinary skill in the art would have a reasonable expectation of success in incorporating the multiple columns of Overton into the miniaturized chromatograph apparatus of Isaka because Overton taught that multiple columns may be incorporated into chromatograph apparatuses. The examiner alleges that this suggests that the use of multiple columns in chromatograph apparatuses is well within ordinary skill. Office Action of December 10, 2001, p. 6. However, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

When considered in its entirety, Overton includes a teaching that its columns are interconnected to facilitate the selection of the column through which the sample is conveyed. Overton discloses that the columns are interconnected using pneumatic valves. Therefore, any modification of Isaka to include the teachings of Overton would include interconnected columns. However, the matrices of the claimed invention are unconnected, porous regions and, therefore,

are not interconnected. In addition, the pneumatic valves of Overton could not be used to interconnect porous columns formed in a silicon substrate.

Third, the obviousness rejection of claim 1 is improper because the cited references do not teach or suggest every limitation of claim 1. Independent claim 1 recites a sample separation apparatus that comprises a substrate and matrices formed in the substrate. The matrices comprise at least two distinct, unconnected porous regions that extend at least partially across the substrate. In addition, at least one detector is fabricated on the substrate in communication with at least one of the at least two porous regions.

Neither Isaka nor Overton discloses that the matrices comprise two or more distinct, unconnected porous regions. Rather, Isaka teaches a chromatograph that includes a single, porous column formed in a silicon substrate and, therefore does not disclose two or more distinct unconnected porous regions. Overton teaches a gas chromatograph that includes interconnected, conventional chromatography columns. These columns are not matrices formed in the substrate because the columns are not matrices that comprise distinct, unconnected porous regions in the substrate. Furthermore, the columns of Overton are interconnected and, therefore, do not comprise unconnected porous regions.

In addition, the cited references do not teach or suggest a sample separation apparatus that includes at least one detector fabricated on the substrate and in communication with at least one porous region. The detector of the chromatograph of Isaka is separate from the substrate, while the detector of the chromatograph of Overton is separate from the columns.

Since the cited references do not establish the three requirements of Section 103, it is respectfully submitted that claim 1 is not obvious over Isaka and Overton. Therefore, the rejection of claim 1 should be withdrawn.

Claims 3-5, 7-11, 13, 16, 18-20, 25, 26, and 29 are each allowable, among other reasons, as depending either directly or indirectly from allowable claim 1.

Claim 5 is further allowable since neither Isaka nor Overton teaches or suggests a sample separation that includes at least two porous regions, at least one of which extends only partially across the substrate. As discussed previously, the chromatograph of Isaka includes only one column. In addition, Overton does not teach or suggest that the columns comprise porous

regions in the substrate. Therefore, no substrate exists for the columns of Overton to extend across only partially.

Claims 8 and 26 are each further allowable since neither reference teaches or suggests a capture component or capture substrate. While Isaka discloses using an enzyme, one of skill in the art would be aware that the enzyme is not a capture component or capture substrate. Rather, the enzyme of Isaka briefly interacts or reacts with the substrate to convert the substrate into a different product. The enzyme then releases the product, allowing the product to migrate through a microchannel. The product is then detected upon exiting the microchannel. In contrast, the capture component or capture substrate recited in claims 8 and 26 captures an analyte, thereby preventing further migration of the analyte, and need not substantially alter the analyte into a different product.

Claim 11, which depends from claims 1, 5, and 10, is additionally allowable since neither Isaka nor Overton teaches or suggests a sample separation apparatus that includes reaction regions situated immediately along lengths of each of at least two porous regions, where each reaction region is located substantially the same distance from an end of its respective column.

Claim 16, which recites that the sample separation apparatus include a processor on the substrate, is further allowable as neither Isaka nor Overton teaches or suggests that a processor is located on a substrate in which at least two porous regions are formed. Isaka lacks any teaching or suggestion that it would be desirable to include a processor on the substrate of its device. Overton lacks any teaching that the conventional chromatography columns could be formed in a substrate. Moreover, it is respectfully submitted that since no art has been cited that demonstrates that the inclusion (not necessarily fabrication) of a processor on the substrate itself would have been an obvious design choice, the subject matter recited in claim 16 is not obvious.

Independent claim 30 recites a separation apparatus that includes a substrate, at least two distinct, unconnected capillary columns formed in the substrate, and a detector fabricated on the substrate and situated adjacent at least one of the capillary columns.

As discussed previously, neither Isaka nor Overton teaches or suggests a separation apparatus that includes at least two distinct, unconnected capillary columns. Rather, Isaka teaches a chromatograph that includes a single, porous column formed in a silicon substrate and

Overton teaches a miniaturized chromatograph that includes multiple columns. Overton teaches that these columns are interconnected. Therefore, the multiple columns of Overton are not unconnected as recited in claim 30.

In addition, as discussed previously, neither Isaka nor Overton teaches or suggests a separation apparatus that includes a detector fabricated on the substrate and situated adjacent to at least one of the capillary columns. Isaka lacks any teaching or suggestion of a detector, while Overton lacks a substrate on which a detector could be fabricated.

As Isaka and Overton do not teach or suggest every element of claim 30, it is respectfully submitted that claim 30 is allowable under Section 103.

Claims 31, 32, 34, 35, 38, 39, 43, 46, and 48-50 are allowable, among other reasons, as depending either directly or indirectly from allowable claim 30.

Claim 35 is further allowable because the enzyme disclosed in Isaka is not a capture component or capture substrate. Rather, as those of skill in the art are aware, an enzyme briefly interacts with a substrate to convert the substrate into a product. In other words, the enzyme releases the product, permitting the product to continue migrating through a microchannel. The product is then detected upon exiting the microchannel. By way of contrast, a capture component or capture substrate of the type recited in claim 35 reacts with an analyte by capturing the analyte, preventing further migration of the analyte, and need not substantially alter the analyte.

Claim 46 is further allowable because Isaka does not include any teaching or suggestion of multiple columns and Overton does not teach or suggest that two of the multiple columns may have substantially equal lengths.

Claim 48 is also allowable because Isaka does not include any teaching or suggestion of multiple columns and Overton does not teach or suggest that two of the multiple columns may have substantially equal surface areas.

Claim 49 is further allowable because Isaka does not include any teaching or suggestion of multiple columns and Overton does not teach or suggest that two of the multiple columns may have substantially equal volumes.

Independent claim 51 recites a miniature chromatograph that includes a substrate and porous matrices formed in the substrate that comprise at least two distinct, unconnected capillary columns.

For the reasons discussed above, Isaka and Overton do not teach or suggest a miniature chromatograph that includes at least two distinct, unconnected capillary columns. The teachings of Isaka are limited to a chromatographic separation device with a single porous column formed in a silicon substrate, while Overton discloses that the multiple columns are interconnected.

As Isaka and Overton do not teach or suggest every element of claim 51, it is respectfully submitted that claim 51 is allowable under Section 103.

Dependent claims 52-56 are allowable, among other reasons, as depending from allowable claim 51.

Independent claim 64 recites an analyte detection apparatus that includes a substrate comprising silicon. Matrices are formed in the substrate and comprise at least two distinct, unconnected porous columns that are continuous with a surface of the substrate.

Neither Isaka nor Overton teaches or suggests an analyte detection apparatus that includes at least two distinct, unconnected porous columns. As discussed previously, the chromatograph of Isaka includes a single column, while the multiple columns of the chromatograph of Overton are interconnected.

As Isaka and Overton do not teach or suggest every element of claim 64, it is respectfully submitted that claim 64 is allowable under Section 103.

Claims 66, 69-71, and 73 are allowable, among other reasons, as depending either directly or indirectly from allowable claim 64.

Claim 66 is further allowable because neither Isaka nor Overton teaches or suggests a capture substrate. As explained previously, the enzyme disclosed in Isaka only briefly interacts or reacts with the substrate to convert the substrate into a different product. The enzyme then releases the product, allowing the product to migrate through a microchannel. The product is then detected upon exiting the microchannel. By way of contrast, the capture substrate recited in claim 66 reacts with an analyte by capturing the analyte, preventing further migration of the analyte, and need not substantially alter the analyte.

Obviousness Rejection Based on Isaka in View of Overton and Further in View of Miura

Claims 14, 15, 17, 21, 40, 41, 44, 54, and 55 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Miura. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka and Overton are summarized above.

Miura teaches, among other things, a small-scale liquid chromatograph that includes a silicon substrate and a single, coiled column formed in the substrate. A detector, such as a field effect transistor, is positioned downstream of the column.

The combination of Isaka, Overton, and Miura does not remedy the deficiencies previously discussed regarding the combination of Isaka and Overton. Specifically, Miura does not provide any suggestion or motivation to combine the cited references to produce the claimed invention. In addition, Miura does not provide a reasonable expectation that the combination of references would be successful. Finally, Miura does not teach or suggest the claim limitations that are lacking from the combination of Isaka and Overton. Therefore, independent claims 1 and 30 are allowable for the reasons previously discussed.

Claims 14, 15, 17, and 21 are each allowable, among other reasons, as depending from allowable claim 1.

Claim 17 is additionally allowable since Isaka, Overton, and Miura do not teach or suggest a memory device on a substrate of the chromatographs. Isaka does not disclose any memory device. While Overton and Miura disclose using memory devices, Miura discloses that its memory device is positioned downstream of the column and Overton shows that its detector is located after the column.

The examiner asserts that since Overton and Miura do not specifically exclude the possibility that the memory device is disposed on the substrate, the memory device could, in fact, be disposed on the substrate. However, this assertion does not amount to a teaching or suggestion that the memory device is located on the substrate. In addition, this does not recognize that Miura discloses that its memory device is downstream of the column and Overton discloses that its memory device is positioned after the column. Applicant respectfully submits

that if the inclusion of a memory device on the substrate of a sample separation apparatus is an obvious design choice, the Office is respectfully invited to cite a reference that discloses a sample separation apparatus with a memory device on the substrate, as recited in claim 17.

Claim 21 is further allowable since Isaka, Overton, and Miura do not teach or suggest a vacuum source in operative communication with a porous region. Miura only teaches the use of positive pressure to facilitate the movement of a sample through the column. Column 10, lines 1-34. The examiner asserts that claims 21 and 41 do not exclude positive pressure. However, these claims recite a vacuum source, which is inherently a source of negative pressure.

Claims 40, 41, and 44 are each allowable, among other reasons, as depending either directly or indirectly from allowable claim 30.

Claim 41 is also allowable because Isaka, Overton, and Miura fail to teach or suggest a vacuum source in operative communication with a porous region. Miura only teaches the use of positive pressure to facilitate the movement of a sample through the column thereof. Column 10, lines 1-34.

Claim 44 is further allowable since Isaka, Overton, and Miura do not teach or suggest a sample separation apparatus that includes a memory device on a substrate, as previously discussed.

Claims 54 and 55 are each allowable, among other reasons, as depending from allowable claim 52.

In light of the foregoing reasons, it is respectfully requested that the Section 103 rejection of claims 14, 15, 17, 21, 40, 41, 44, 54, and 55 be withdrawn.

Obviousness Rejection Based on Isaka in View of Overton and Further in View of Wang

Claims 21 and 41 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Wang. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka and Overton are summarized above.

Wang teaches a thermal isolation system that includes, among other things, a chamber within which temperature and pressure may be controlled. A separation device, such as a miniature chromatographic column, may be disposed within the chamber.

It is respectfully submitted that Wang does not cure the deficiencies discussed above with Isaka and Overton. Specifically, Wang does not provide any additional suggestion or motivation to combine the cited references to produce the claimed invention, provide a reasonable expectation that the combination of references would be successful, or teach or suggest the claim limitations that are lacking from the combination of Isaka and Overton. Therefore, independent claims 1, 30, 51, and 64 are allowable for the reasons previously discussed.

Claim 21 is allowable, among other reasons, as depending from allowable claim 1. Claim 21 is further allowable since Isaka, Overton, and Wang do not teach or suggest a vacuum source operatively in communication with an end of the chromatography column. In contrast, the vacuum of Wang is used to vary the pressure within a chamber in which the column has been placed, not to draw a sample through the column. Column 1, line 63-Column 2, line 4, and Column 2, lines 29-41.

Claim 41 is allowable as depending from allowable claim 30. Claim 41 is further allowable because Isaka, Overton, and Wang fail to teach or suggest a vacuum source operatively in communication with an end of a chromatography column.

In light of the foregoing reasons, it is respectfully requested that the Section 103 rejection of claims 21 and 41 be withdrawn.

Obviousness Rejection Based on Isaka in View of Overton and Further in View of Turner

Claims 33 and 74 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Turner. Applicant respectfully traverses this rejection.

The teachings of Isaka, Overton, and Turner are summarized above.

It is respectfully submitted that Turner does not cure the deficiencies discussed above with Isaka and Overton. Specifically, Turner does not provide any suggestion or motivation to

combine the cited references to produce the claimed invention, provide a reasonable expectation that the combination of references would be successful, or teach or suggest the claim limitations that are lacking from the combination of Isaka and Overton. Therefore, independent claims 1, 30, 51, and 64 are allowable for the reasons previously discussed.

It is respectfully submitted that claim 33 is allowable, among other reasons, as depending from allowable claim 30. Claim 74 is allowable, among other reasons, as depending from allowable claim 64.

Obviousness Rejection Based on Isaka in View of Overton and Further in View of Northrup

Claims 22-24 and 42 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3 through 5, 7 through 11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Northrup. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka and Overton are summarized above.

Northrup discloses, among other things, an electrophoretic separation device that includes porous columns formed internally within a silicon substrate. Electrodes are positioned at opposite ends of the substrate so as to facilitate the movement of the constituents of a sample along the lengths of the columns. Northrup also discloses methods for fabricating an electrophoretic separation device.

It is respectfully submitted that Northrup does not cure the deficiencies discussed above with Isaka and Overton. Specifically, Northrup does not provide any suggestion or motivation to combine the cited references to produce the claimed invention, provide a reasonable expectation that the combination of references would be successful, or teach or suggest the claim limitations that are lacking from the combination of Isaka and Overton. The examiner alleges that it would have been obvious to incorporate the electrodes of Northrup with the teachings of Isaka and Overton to produce the claimed invention. However, since Northrup does not cure the previously discussed deficiencies, independent claims 1, 30, 51, and 64 are allowable for the reasons previously discussed.

Claims 22-24 are allowable, among other reasons, as depending from allowable claim 1.
Claim 42 is allowable, among other reasons, as depending from allowable claim 30.

In light of the foregoing reasons, it is respectfully requested that the Section 103 rejection of claims 22-24 and 42 be withdrawn.

Obviousness Rejection Based on Isaka in View of Overton and Further in View of Swedberg

Claims 27, 28, 36, 37, 67, and 68 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and further in view of Swedberg. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka and Overton are summarized above.

Swedberg teaches a miniaturized separation apparatus including a column within which a porous quantity of biocompatible material, such as nylon, cellulose, polymethylmethacrylate, polyacrylamide, or agarose, may be disposed. Column 27, lines 37-40. These biocompatible materials are placed into an open column to separate the constituents of biological samples.

It is respectfully submitted that Swedberg does not cure the deficiencies discussed above with Isaka and Overton. Specifically, Swedberg does not provide any suggestion or motivation to combine the cited references to produce the claimed invention, provide a reasonable expectation that the combination of references would be successful, or teach or suggest the claim limitations that are lacking from the combination of Isaka and Overton. Since Swedberg does not cure the previously discussed deficiencies, independent claims 1, 30, 51, and 64 are allowable for the reasons previously discussed.

Claims 27 and 28 are allowable, among other reasons, as depending from allowable claim 1. Claims 36 and 37 are allowable, among other reasons, as depending from allowable claim 30. Claims 67 and 68 are allowable, among other reasons, as depending from allowable claim 64.

In light of the foregoing reasons, it is respectfully requested that the Section 103 rejection of claims 27, 28, 36, 37, 67, and 68 be withdrawn.

Obviousness Rejection Based on Isaka in View of Overton and, if Necessary, Northrup in View of Turner, and Further in View of Sunzeri

Claims 6, 57-63, and 72 stand rejected under Section 103 as being unpatentable over Isaka in view of Overton, as applied to claims 1, 3-5, 7-11, 13, 16, 18-20, 25, 26, 29 through 32, 34, 35, 38, 39, 43, 46, 48-53, 56, 64, 66, 69-71, and 73 above, and, if necessary, Northrup in view of Turner and further in view of Sunzeri for reasons of record. Applicant respectfully traverses this rejection, as hereinafter set forth.

The teachings of Isaka, Overton, Northrup, and Turner are summarized above.

Sunzeri teaches a method for analyzing the constituents of human biological fluids. A labeled specific binding pair member is added to a human biological fluid to effect binding between an analyte in the human biological fluid and the specific binding pair member. The constituents of the human biological fluid, including complexes of the analyte and the specific binding pair member, are separated by way of known capillary electrophoresis techniques. The separation obtained by way of capillary electrophoresis is then compared to a control, which provides a standard for quantitation by indicating the position where the analyte would have been present if it had not been bound by the labeled specific binding pair member. The specific binding pair member is not immobilized to the matrix of the capillary electrophoresis substrate but, rather, is permitted to travel therethrough with the bound analyte.

Sunzeri does not cure the deficiencies discussed above with Isaka and Overton. Specifically, Sunzeri does not provide any suggestion or motivation to combine the cited references to produce the claimed invention, provide a reasonable expectation that the combination of references would be successful, or teach or suggest the claim limitations that are lacking from the various combinations of Isaka, Overton, Northrup, and Turner. Therefore, independent claims 1, 57, and 64 are allowable.

Claim 6 is allowable as depending from allowable claim 1 and further for the reasons provided below with respect to claim 57.

Independent claim 57 recites an electrophoretic apparatus that includes a substrate, at least one sample column formed in the substrate, and a control column. The at least one sample

column comprises a first porous matrix. The control column comprises a second porous matrix that includes a plurality of pores formed in the substrate.

It is respectfully submitted that independent claim 57 is allowable over the combination of Isaka with Overton and Sunzeri for at least two reasons: first, one of ordinary skill in the art would not have been motivated to combine the teachings of Isaka, Overton, and Sunzeri in the asserted manner; second, assuming such a combination could have been made, there would have been no reason to expect such a combination to be successful.

With respect to the lack of motivation to one of ordinary skill in the art to combine the teachings of Isaka, Overton, and Sunzeri, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to combine Isaka and Overton for the reasons provided previously herein: Isaka describes porous columns formed in a substrate while Overton teaches an apparatus that includes conventional, open channeled chromatography columns, which are free-standing and, thus, are not formed in a substrate. Sunzeri does not include any teachings or suggestions that remedy the motivation lacking from Isaka, Overton, and the knowledge that was generally available in the art before the priority date for the referenced application.

Additionally, it is submitted that one of ordinary skill in the art would not have been motivated to use a control column, such as that described in Sunzeri, in the chromatography apparatus of either Isaka or Overton. Insofar as Applicant is aware, chromatography apparatus do not include control columns as control columns would not provide any useful information due to the manner in which the constituents of a sample are separated by such columns, exiting such columns separately from one another for subsequent, separate identification.

It is further submitted that Sunzeri does not include any teaching or suggestion that would provide one of ordinary skill in the art with a reasonable expectation that the pneumatic valves of the chromatograph described in Overton could be used to connect porous silicon columns of the type described in Isaka.

Therefore, it is respectfully submitted that independent claim 57 is allowable over the combination of Isaka, Overton, and Sunzeri.

Claims 58-63 are allowable as depending from claim 57.

Claim 72 is allowable as depending from claim 64.

Drawings

Applicant will file formal drawings upon receipt of a Notice of Allowance and Issue Fee Due in the application.

CONCLUSION

Claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact applicant's undersigned attorney.

Respectfully Submitted,



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Date: December 10, 2001
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